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US Military Smallpox Vaccination Program Experience

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IN DECEMBER 2002, THE UNITED States implemented a program of smallpox vaccinations for approximately 500 000 military personnel. The directive came as part of a national program of preparedness against biological attack.¹ Preattack vaccination was determined to be the best way to personally protect troops so they can continue their missions.^{2,3} The program was therefore mandatory for designated service members and employees except those with contraindications. This article describes the first 450 293 vaccinations.

METHODS

To develop vaccination policy, the US Department of Defense (DoD) drew from its own physicians, scientists, and administrators³ as well as colleagues in government and academia. The military vaccination program included vaccination for smallpox epidemic response teams (2000-5000 people) to assist with epidemic control and contact tracing in an outbreak, medical teams for hospitals and clinics (10 000-25 000 people) to care for smallpox cases, and operational forces (up to 500 000 people) to preserve critical capabilities.

Education, Training, and Screening

The US Army conducted a medical training conference in October 2002. This conference was videotaped and posted at <http://www.smallpox.army.mil>. Medical directors completed 8 hours of training; physicians and supervising nurses

See also pp 3283, 3290, 3295, and 3306.

Context The United States recently implemented smallpox vaccination of selected military personnel in a national program of preparedness against use of smallpox as a biological weapon. The resumption of smallpox vaccinations raises important questions regarding implementation and safety.

Objective To describe the US military smallpox vaccination program.

Design Descriptive study of the vaccination program from its inception on December 13, 2002, through May 28, 2003.

Setting US Department of Defense (DoD) fixed and field medical treatment facilities on multiple continents and ships at sea.

Subjects US service members and DoD civilian workers eligible for smallpox vaccination.

Main Outcome Measures Numbers of vaccinations and rates of vaccination exemptions, symptoms, and adverse events. Data were collected via reports to headquarters and rigorous surveillance for sentinel events.

Results In 5.5 months, the DoD administered 450 293 smallpox vaccinations (70.5% primary vaccinees and 29.5% revaccinees). In 2 settings, 0.5% and 3.0% of vaccine recipients needed short-term sick leave. Most adverse events occurred at rates below historical rates. One case of encephalitis and 37 cases of acute myopericarditis developed after vaccination; all cases recovered. Among 19 461 worker-months of clinical contact, there were no cases of transmission of vaccinia from worker to patient, no cases of eczema vaccinatum or progressive vaccinia, and no attributed deaths.

Conclusions Mass smallpox vaccinations can be conducted safely with very low rates of serious adverse events. Program implementation emphasized human factors: careful staff training, contraindication screening, recipient education, and attention to bandaging. Our experience suggests that broad smallpox vaccination programs may be implemented with fewer serious adverse events than previously believed.

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completed 6 hours; vaccinating nurses and medics completed 3 hours. Leaders educated vaccine candidates and reinforced messages after vaccination. We provided brochures and curricula as well as customized information services via telephone (877-GET-VACC) or e-mail (vaccines@amedd.army.mil).

To identify people with contraindications to vaccination,⁴⁻⁸ clinicians used a standardized recording form to screen for skin conditions, immunosuppression, pregnancy or breastfeeding, and allergies (<http://www.smallpox.army.mil/resource/forms.asp>). Completed forms were reviewed by medics, nurses, nurse

practitioners, physician assistants, and physicians in a triaged manner before vaccination. The DoD used its periodic testing program for human immunodeficiency virus (HIV) infection to identify that contraindication. Women were advised that pregnancy is a contraindication, asked about pregnancy status, and provided pregnancy tests, if requested.

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Infection Control

Each hospital and clinic established bandage evaluation stations.^{6,7} For non-health care workers, infection control practices focused on bandages (eg, simple Band-Aid type bandages with 20 × 25-mm pads), sleeves, and hand washing. To calculate time at risk, each vaccinee was assumed capable of spreading vaccinia for 21 days after vaccination.

Quality Control and Implementation

The licensed full-strength smallpox vaccine (Dryvax, Wyeth Laboratories, Marietta, Pa) containing the New York City Board of Health strain of vaccinia was used in this program.^{4,8} First-time vaccination entailed 3 punctures with a bifurcated needle. Previous vaccinees received 15 punctures. Those who did not respond with a major reaction as defined by the World Health Organization (WHO)^{5,8} were vaccinated again.

Smallpox vaccinations began at 4 pilot sites: Walter Reed Army Medical Center, Washington, DC; Aberdeen Proving Ground, Md; Wilford Hall Air Force Medical Center, Lackland Air Force Base, San Antonio, Tex; and the National Naval Medical Center, Bethesda, Md. For quality control, clinics tracked the vaccination response rates of the first 25 people for each vaccinator.

Surveillance for Adverse Events

Postvaccination surveillance assesses the screening process, health events shortly after vaccination, and events months or years after vaccination. Vaccine Health-care Centers evaluate complex cases. A registry was established for women vaccinated before recognition of pregnancy, a joint project with the Centers for Disease Control and Prevention (CDC).⁹ An independent safety monitoring panel, coordinated by the Armed Forces Epidemiological Board and the Advisory Committee on Immunization Practices, reviews weekly updates.¹⁰ We shared experience weekly with CDC and state health departments.

Adverse events reported here were collected via symptom surveys from

each vaccinated member of the first 7 operational units vaccinated (n = 526), plus reports to headquarters and rigorous surveillance for sentinel events. Frequencies are reported for the units described. The number of adverse events identified was divided by the size of the vaccinated cohort. Exact confidence intervals were calculated for Poisson distribution of rare events.

Definitions of adverse events were derived from expert consultants. Generalized vaccinia involved vesicles or pustules in several locations distant from the vaccination site that evolved like vaccinia vesicles and pustules. Encephalitis involved altered consciousness for at least 24 hours with more than 5 white blood cells/μL in cerebrospinal fluid. Myopericarditis involved chest pain and elevated cardiac enzymes (eg, troponin, creatine kinase-MB), as reported by Halsell et al¹¹ elsewhere in this issue of THE JOURNAL.

RESULTS

From December 13, 2002, through May 28, 2003, a total of 450 293 personnel were vaccinated against smallpox with the New York City Board of Health strain (TABLE 1). Vaccinations occurred in fixed and field medical facilities in North America, Europe, Asia, Africa, and Oceania and on ships at sea. At peak, more than 50 000 vaccinations were administered per week.

The median age of vaccinees was 26 years and 87% were men; 70.5% were receiving their primary (first) vaccination. Contraindications due to either personal conditions or conditions among household contacts varied by military unit, temporarily deferring vaccination in 11% to 34% of eligible personnel. Skin conditions predominated, followed by pregnancy and immune conditions. Exemptions ranged from 4.9% to 7.8% among deployed units, where household contacts were not present.

Military immunization clinics reported high rates of successful vaccination (major reactions, response rates).^{3,8} Some clinicians sought advice to confirm that small dermal responses fit the WHO definition. At the 4 pilot clinics,

Table 1. Demographic Characteristics of Smallpox Vaccinees, December 13, 2002, to May 28, 2003 (n = 450 293)*

Characteristics	
Age, y	
Mean (SD)	28.8 (8.3)
Median (range)	26 (17-76)
Sex	
Female	57 460 (12.8)
Male	392 833 (87.2)
Ethnicity	
Non-Hispanic	394 857 (87.7)
Hispanic	39 461 (8.8)
Unspecified	15 975 (3.5)
Race	
White	328 612 (73.0)
African American	80 796 (17.9)
Asian/Pacific Islander	10 459 (2.3)
Native American	3927 (0.9)
Other	26 499 (5.9)
Vaccination status	
Primary vaccinees	317 637 (70.5)
Revaccinees	132 656 (29.5)

*Vaccinations continue. Current number of vaccinees is larger. Data are No. (%) unless otherwise specified.

971 of 1017 primary vaccinees (95.5%) were successfully vaccinated with a single vaccination. Among 975 people who had been vaccinated decades earlier, 934 (95.8%) were successfully vaccinated with a single vaccination. Around the world, 2 vaccine recipients were treated successfully with epinephrine for acute allergic events.

Vaccinated health care workers remained on the job (including surgery and labor and delivery), using bandages, sleeves, hand washing, and evaluation stations. Vaccinated workers were not prohibited from caring for immunocompromised patients. No transmission of vaccinia from a health care worker to a patient was identified during an estimated 19 461 worker-months of interaction with patients. Conversely, no vaccinee later treated as a patient transmitted vaccinia to a health care worker.

Expected temporary symptoms occurred after vaccination, notably itching, muscle ache, "feeling lousy," headache, swollen lymph nodes, irritation from bandages, subjectively reported fever, and local rash (TABLE 2). Approximately 1% of vaccine recipients developed cutaneous eruptions beyond the vaccination site.

Among carefully observed workers at Walter Reed Army Medical Center, the frequency of vaccinated workers

taking sick leave was 3.0% (16/530), typically 8 to 12 days after vaccination. The most common duration was 1 day (mean, 1.5 days; maximum, 4 days). Eleven of 198 primary vaccinees (5.5%) took sick leave, as did 5 of 332 revaccinees (1.5%). Among 16 deployed US Air Force clinics serving 20272 vaccinees, 0.5% took 1 or 2 days of sick leave after vaccination. Other sites reported similar results.

Skin eruptions or rashes caused concern among clinicians. These rashes were generally mild and treated symptomatically. In 16 cases with maculopapular rashes, vaccine recipients were hospital-

ized, in part because of uncertainty about contagiousness or clinical course. This was especially true early in the program. In each case, patients returned to duty promptly. Subsequent patients of comparable acuity were typically not hospitalized. Six service members developed cellulitis as diagnosed by physicians, were treated with intravenous antibiotics, and returned to duty.

Noteworthy adverse reactions are summarized in TABLE 3. Thirty-six vaccine recipients may qualify as mild cases of generalized vaccinia (based on reports to the Vaccine Adverse Event Reporting System), all among primary vaccinees (35 men and 1 woman). Each was treated symptomatically (eg, with antihistamines, analgesics, antipyretics) and returned to duty. Nine were hospitalized for observation, notably by clinicians seeing their first such patient. Erythema multiforme major confirmed by skin biopsy developed in a 20-year-old service member 19 days after receiving smallpox and several other vaccines. This case was deemed to possibly be associated with smallpox vaccination, given multiple possible causes.

Thirty-eight reports of inadvertent implantation ("autoinoculation") of the skin were submitted, with varying certainty of association to vaccinia. Affected sites included chest, cheek, arm, finger, wrist, genitals, groin, and mouth. Ten others involved possible or probable ocular vaccinia, typically treated with triflu-

ridine eye drops. Four (skin=3, eye=1) were confirmed by culture and polymerase chain reaction (PCR) test.

We identified 21 instances of contact transfer of vaccinia, all involving primary vaccinees, in 306673 person-months of potential contact with vaccinia. These included 10 spouses, 2 children, 5 intimate contacts, and 4 friends. No cases of contact vaccinia were observed in patients. The most commonly named mechanism involved failure to observe bandaging discipline (eg, touching vaccination sites, touching bandages). Most cases were clinically mild, manifesting as pustules on arms, shoulders, or hips. In 2 cases, conjunctivitis or blepharitis developed; each was treated with trifluridine. One was treated with vaccinia immune globulin (VIG) and discharged from the hospital the following day.¹² Hundreds of thousands of vaccinees flew from North America to southwest Asia before their vaccinia scabs had fallen off, yet no spread to passengers or flight attendants was reported.

Two cases of encephalitis as defined by attending physicians presented 7 and 9 days after vaccination, the first in a 23-year-old after primary vaccination and the second in a 38-year-old after revaccination. In both cases, the patients recovered and returned to duty. The first case met objective criteria for encephalitis but the second did not. Diagnostic studies in the first case by viral culture and PCR did not establish vaccinia or 9 other viruses as a cause. Twenty-three other neurologic events occurred, 1 fatal. Their association to vaccination is unclear, given multiple possible causes (neuromuscular weakness or palsy=6, seizures=6, meningitis=4, optic neuritis=2, demyelinating conditions [eg, Guillain-Barré syndrome]=2, altered cognition=2, transient visual defect=1).

Thirty-seven suspected, probable, or confirmed cases diagnosed as acute myopericarditis developed in male primary vaccinees aged 21 to 33 years at 7 to 19 days after vaccination. In each of the initial 18 cases described by Halsell et al,¹¹ the patient presented with chest pain, and elevated cardiac enzymes were found;

Table 2. Expected Temporary Symptoms and Short-term Outcomes After Smallpox Vaccination*

	No. (%)
Symptoms	
Local itching	313 (60)
Muscle ache	110 (21)
Feeling lousy	109 (20)
Headache	95 (18)
Swollen lymph nodes	74 (14)
Bandage reaction	39 (7.4)
Itchy all over	29 (5.5)
Fever (subjective)	28 (5.3)
Local rash	28 (5.3)
Body rash	8 (1.1)
Outcomes	
Took medication	89 (17)
Restricted activity	7 (1.3)
Outpatient visit	4 (0.8)
Missed work	1 (0.2)

*Via survey completed 6 to 8 days after vaccination among all 526 vaccinated personnel assigned to the 2nd (New York), 35th (West Virginia), and 103rd (Alaska) Civil Support Teams; Aberdeen Proving Ground, Md; Fort Jackson, SC; Lackland Air Force Base, Tex; and Schofield Barracks, Hawaii.

Table 3. Noteworthy Adverse Events After Smallpox Vaccination

Event Type	No. of Events	DoD Rate per Million Vaccinees (95% Confidence Interval)	Historical Rate per Million Vaccinees
Mild or temporary			
Generalized vaccinia, mild	36	80 (63-100)	45-212*
Erythema multiforme	1	NA	NA
Inadvertent inoculation, self	48†	107 (88-129)	606*
Vaccinia transfer to contact	21	47 (35-63)	8-27*
Moderate or serious			
Encephalitis	1	2.2 (0.6-7.2)	2.6-8.7*
Acute myopericarditis	37	82 (65-102)	100‡
Eczema vaccinatum	0	0 (0-3.7)	2-35*
Progressive vaccinia	0	0 (0-3.7)	1-7*
Death	0	0 (0-3.7)	1-2*

Abbreviations: DoD, US Department of Defense; NA, not available.

*Based on adolescent and adult smallpox vaccinations from 1968 studies (both primary and revaccination).²⁷⁻²⁹

†Includes 38 inadvertent inoculations of the skin and 10 of the eye.

‡Based on case series in Finnish military recruits given the Finnish strain of smallpox vaccine.³⁰

electrocardiogram (ECG) and echocardiogram findings varied. Clinical conditions ranged from mild (no ECG or echocardiogram changes) to severe (1 case of transient lowered ejection fraction).¹³ All survived and either have or are expected to return to duty.

Eight additional cardiac events occurred 2 to 12 days after vaccination (myocardial infarction=4, angina=2, coronary artery spasm=1, atrial fibrillation=1). A 55-year-old male service member died after a myocardial infarction 5 days after vaccination. Autopsy findings showed 3-vessel coronary occlusion, left ventricular hypertrophy, and cardiomegaly.¹³

Despite extensive efforts to avoid vaccinating women who were pregnant, 85 of 62622 vaccine-eligible women (0.14%) were vaccinated before they knew they were pregnant. Once found to be pregnant, these women were offered clinical support and medical counseling, and enrolled in a prospective registry.^{9,14}

Ten male service members aged 23 to 37 years were vaccinated before recognition that they were infected with HIV. Each responded successfully to vaccination and their sites healed at the expected pace. Later studies showed that their CD4 cell counts ranged from 303 to 751 cells/ μ L shortly after vaccination.

One service member received extensive burns 5 days after vaccination. To preclude vaccinia complications of his recovery, this man received VIG prophylactically. He developed new vesicles 13 days after receiving VIG, but the vesicles tested negative for vaccinia by PCR and culture. Another burned service member whose vaccination site had scabbed over was not treated with VIG. He did not develop other vaccinia lesions.

No cases of eczema vaccinatum or progressive vaccinia occurred. We attribute no deaths to smallpox vaccination to date.¹³

COMMENT

Smallpox affected soldiers and sailors for centuries.^{4,8,15,16} United States ser-

vice members received smallpox vaccination from the War of 1812 until 1990.^{17,18} A 1977 report notes 54 hospitalizations per 1 million vaccinations (mainly secondary infections).¹⁹ Between 1965 and 1975, the US Air Force recorded 6 encephalitis cases after vaccination.¹⁹ Service members spread vaccinia to several civilians in the 1980s.²⁰⁻²³ After extensive searching, we could not confirm any deaths due to smallpox vaccination of military personnel since 1943.^{17-19,24-26}

Surveillance of the current US military smallpox vaccination program identified an increased risk of myopericarditis after smallpox vaccination.¹¹ We believe myopericarditis resulted from smallpox vaccination in the 1960s but was underrecognized because cardiac enzyme and imaging technologies were still being developed. We observed ischemic events after vaccination but at a rate that was less than the age-adjusted rate expected among unvaccinated military personnel. Allowing for underreporting, we found no causal association between vaccination and ischemic events.

The incidence of adverse events in Table 3 reflects rates largely below those reported in the 1960s and 1970 (although such comparisons must be interpreted with caution given differences in age, prior vaccination, population immunity, and other variables).²⁷⁻²⁹ In addition, underreporting may affect our rates and historical rates,²⁷⁻³¹ but our global communications and surveillance would tend to reduce underreporting. Military commanders were vigorous in identifying troops needing treatment. Teleconsultation identified noteworthy cases that may have been missed in earlier eras. Historical rates are not directly applicable to contact transfer because of differences in population immunity and underlying disease.

Our individualized screening for contraindications may explain the lack of eczema vaccinatum or progressive vaccinia.^{6,7} Extensive education may have contributed to low rates of inadvertent inoculation. Interestingly, reports of in-

advertent inoculation from the United States did not differ substantially from rates reported in Asia, where sanitary conditions are rudimentary. Medical officers attributed the low rates overseas to disciplined wearing of long sleeves, attention to personal hygiene, and training. We observed 1 probable case of autoinoculation among 27801 military health care workers, comparable with the 3 confirmed cases reported among 34541 civilian health care workers.³²

Successful implementation of bandage evaluation stations in our health care settings validates this approach.^{6,7} Our experience suggests that no disruption of routine clinical care need occur after vaccination given vigorous infection control.

Similarly, we observed a low rate of contact transfer of vaccinia, despite the close living conditions associated with mobilization and deployment. These conditions are known risk factors for other contagious diseases. Most vaccine recipients used simple bandages, not semipermeable dressings, suggesting the primacy of human factors and postvaccination discipline. Health care workers in both military and civilian settings have been comparably successful in not spreading vaccinia to their contacts.³²

This descriptive report cannot establish the efficacy of the screening, educational, and surveillance methods used because it lacks an explicit control group. Additional efforts will be needed to evaluate the relative efficiency of alternative approaches.

The DoD is responsible for protecting and preserving the health of US service members. We vaccinated with this responsibility in mind. Because smallpox vaccine is associated with temporary unpleasant symptoms and carries a small risk of serious adverse events, we sought to implement our program with due attention to safety. We offer our experience to help the civilian community.

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